

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

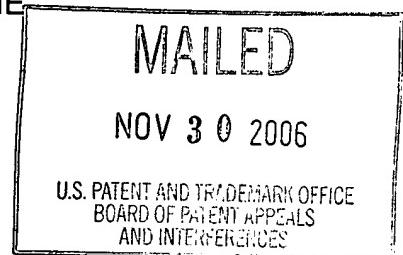
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GRAEME I. BELL, TERRY REISINE
and KAZUKI YASUDA

Appeal No. 2006-1632
Application No. 08/455,683

ON BRIEF



Before SCHEINER, ADAMS and MILLS, Administrative Patent Judges.

SCHEINER, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims directed to assays for screening substances for the ability to interact specifically with an opioid receptor. The examiner has rejected the claims as lacking adequate written descriptive support in the specification. We have jurisdiction under 35 U.S.C. § 134. We will reverse this rejection.

Background

"Opioids are used clinically in the management of pain, but their use is limited by a constellation of undesirable side effects, including respiratory depression, miosis, decreased gastrointestinal motility, sedation, nausea . . . [and] their potential for dependence and abuse." Specification, page 4.

“Pharmacological studies have suggested that there are at least four major classes of opioid receptors, designated δ, κ, μ and σ” which “differ in their affinity for various opioid ligands and in their cellular distribution” (*id.*, page 3).

Additional studies “suggest [that] the clinical effects of opioids are mediated via a variety of receptors and that the therapeutic effects and the undesirable side effects of opioids are mediated by different receptor (sub)types” (*id.*, page 4). “Therefore,” according to appellants, “the therapeutic and side effects of opioids can be separated with the use of more selective agents for receptor subtypes” (*id.*).

The specification describes, among other things, “isolated and purified polynucleotide[s] . . . compris[ing] the nucleotide base sequence[s] of [murine] kappa opioid receptor, e.g., mORK1 (SEQ ID NO:1) [and] human kappa opioid receptor (SEQ ID NO:11)” (*id.*, page 12). SEQ ID NO:11 is only a “[p]artial genomic sequence for a human kappa opioid receptor” (*id.*, page 24), but “the amino acid sequences of the human and mouse kappa receptors are highly homologous” (*id.*, page 135). Of 293 aligned amino acid residues from the two sequences, “281 residues are identical and 6 residues involve conservative substitutions” (*id.*).

According to appellants, κ-selective agonists and antagonists bind to physically distinct regions of the κ receptor” (*id.*, page 167), as do “selective and non-selective agonists” (*id.*). Moreover, “[t]he second extracellular loop of the κ receptor contains a binding domain for κ-selective agonists” (*id.*).

Discussion

The Claims

Claims 97 and 109 are representative of the subject matter on appeal and read as follows:

97. A process of screening a substance for its ability to specifically bind to an opioid receptor, said process comprising the steps of:

- a) expressing a recombinant opioid receptor polypeptide encoded by a nucleic acid sequence comprising at least 30 contiguous bases of SEQ ID NO:11;
- b) contacting said substance with the recombinant opioid receptor polypeptide; and
- c) detecting whether said substance has an ability to specifically bind to said recombinant opioid receptor polypeptide.

109. A process of isolating a substance with an ability to act as a specific agonist of a kappa opioid receptor, said process comprising the steps of:

- a) providing a recombinant opioid receptor polypeptide comprising the second extracellular loop comprising the amino acid sequence of residues 111 through 136 of SEQ ID NO:12 and encoded for by a nucleic acid sequence comprising at least 30 contiguous bases of SEQ ID NO:11;
- b) contacting said recombinant opioid receptor polypeptide with a composition comprising said substance;
- c) detecting whether said substance has an ability to agonize said recombinant opioid receptor polypeptide; and
- d) isolating said substance if said substance has an ability to agonize the recombinant opioid receptor polypeptide.

Written Description

Claims 97-102, 109, 112-114, 123 and 137-156 stand rejected under 35 U.S.C. §112, first paragraph as lacking adequate written descriptive support. These claims are directed to assays for screening substances for the ability to interact specifically with an

opioid receptor, using recombinant opioid receptor polypeptides encoded by nucleic acids comprising at least 30 contiguous bases of SEQ ID NO:11, in some cases, contiguous bases encoding the second extracellular loop of the kappa receptor. None of the claims requires the use of a full length receptor.

The examiner rejected claims 97-102, 109, 112-114, 123 and 137-156 under 35 U.S.C. § 112, first paragraph, because “[t]he claims are worded in such a way that they encompass screening methods using the full-length kappa opioid receptor encoded by SEQ ID NO:11 which Appellants have not described” (Examiner’s Answer, page 3). The examiner also argued that that 30 contiguous bases of SEQ ID NO:11 “would not . . . necessarily encode the second extracellular loop of the human kappa opioid receptor, which is thought to be essential for ligand binding” (Examiner’s Answer, page 3).

The written description requirement of 35 U.S.C. § 112, first paragraph, does not require a description of the complete structure of every species within a chemical genus. See Utter v. Hiraga, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) (“A specification may, within the meaning of 35 U.S.C. § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.”).

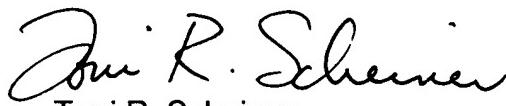
This standard applies to DNA as well. “A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.” University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Here, the polypeptides can be encoded by polynucleotides of various lengths, beginning and ending at different positions on SEQ ID NO:11, but all are defined by sequence. That is, each polypeptide must be encoded by a nucleic acid molecule that contains a region that corresponds exactly to a segment of SEQ ID NO:11. This is true whether the nucleic acid molecule includes additional flanking residues or not. Moreover, we note residues representing the second extracellular loop of the kappa receptor are specifically recited in those claims that require that region of the receptor (e.g., claim 109).

We agree with appellants that the specification adequately describes structural features which are common to members of the genus required by the claims, and which allow one skilled in the art to visualize or recognize the members of the genus. Cf. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.

Accordingly, the rejection of the claims as lacking adequate written descriptive support under 35 U.S.C. § 112, first paragraph, is reversed.

REVERSED


Toni R. Scheiner

Administrative Patent Judge)


Donald E. Adams)

Administrative Patent Judge)

) BOARD OF PATENT

) APPEALS AND

) INTERFERENCES


Demetra J. Mills)
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